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Attorneys for Plaintiff TherapeuticsMD, Inc.

UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

THERAPEUTICSMD, INC.,

Plaintiff,

v.

AMNEAL PHARMACEUTICALS, INC., AMNEAL PHARMACEUTICALS, LLC, and AMNEAL PHARMACEUTICALS OF **NEW YORK LLC,**

Defendants.

Civil Action No. 20-5256 (FLW)(TJB) Civil Action No. 20-14933 (FLW)(TJB)

(Filed Electronically)

CONSENT JUDGMENT

Plaintiff TherapeuticsMD, Inc. ("TherapeuticsMD") and defendants Amneal Pharmaceuticals, Inc., Amneal Pharmaceuticals, LLC, and Amneal Pharmaceuticals of New York LLC (together, "Amneal" or "Defendants"), by their undersigned attorneys, hereby stipulate and consent to entry of judgment and an injunction in this action as follows: IT IS this 9th day of December

ORDERED, ADJUDGED, AND DECREED as follows:

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- 1. This Court has jurisdiction over the subject matter of the above action and has personal jurisdiction over the parties for purposes of this action only, including as set forth below in Paragraph 6 of this Consent Judgment.
- 2. As used in this Consent Judgment, the term "Amneal ANDA Product" shall mean a drug product manufactured, imported, sold, offered for sale, marketed, or distributed pursuant to Abbreviated New Drug Application No. 214293 in or for the United States of America, including its territories, possessions, and the Commonwealth of Puerto Rico.
- As used in this Consent Judgment, the term "Patents-in-Suit" shall mean U.S. 3. Patent Nos. 8,633,178; 8,846,648; 8,846,649; 8,987,237; 8,993,548; 8,993,549; 9,006,222; 9,114,145; 9,114,146; 9,301,920; 10,052,386; 10,206,932; 10,639,375; 10,675,288; 10,806,740; 11,033,626; 11,103,513; 11,103,516; and 11,110,099.
- 4. Until expiration of the Patents-in-Suit, Amneal, including any of its successors and assigns, is enjoined from infringing the Patents-in-Suit, on its own part or through any third party on its behalf, by making, having made, using, selling, offering to sell, importing, or distributing the Amneal ANDA Product in or for the United States of America, including its territories, possessions, and the Commonwealth of Puerto Rico, unless and to the extent otherwise specifically authorized by TherapeuticsMD, and is further enjoined from assisting or cooperating with any third parties in connection with any infringement of the Patents-in-Suit by any such third parties in connection with making, having made, using, selling, offering to sell, importing, or distributing any 1 mg/100 mg (estradiol and progesterone) capsule product that references New Drug Application No. 210132 in or for the United States of America, including its territories, possessions, and the Commonwealth of Puerto Rico, unless and to the extent otherwise specifically authorized by TherapeuticsMD.

- 5. Compliance with this Consent Judgment may be enforced by TherapeuticsMD and its respective successors in interest or assigns.
- 6. This Court retains jurisdiction to enforce the terms of this Consent Judgment and to enforce and resolve any disputes related thereto.
- 7. All claims, counterclaims, affirmative defenses, and demands in this action are hereby dismissed with prejudice and without costs, disbursements, or attorneys' fees to any party.
- 8. Nothing herein prohibits or is intended to prohibit Amneal from maintaining any "Paragraph IV Certification" pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) or pursuant to 21 C.F.R. § 314.94(a)(12) with respect to the Patents-in-Suit.
- 9. Nothing herein restricts or is intended to restrict the U.S. Food and Drug Administration from approving Abbreviated New Drug Application No. 214293 or the Amneal ANDA Product.

/s/ Freda L. Wolfson Hon. Freda L. Wolfson, U.S.D.J.

We hereby consent to the form and entry of this Judgment:

Dated: December 8, 2021

By: s/ Charles M. Lizza

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